UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

KONINKLIJKE PHILIPS ELECTRONICS NV, Plaintiff, v. CARDIAC SCIENCE OPERATING COMPANY, Defendant.	CASE NO. 2:08-CV-00543-MJP FINDINGS OF FACT AND CONCLUSION OF LAW

This matter comes before the Court after it held a one-day trial on January 18, 2011. Having heard the testimony of two experts and viewed all of the materials submitted at trial, the Court concludes that the Owen application lacks an adequate written description for claims 5-9, 11, 16-18, 23-25, 27-30, and 32-33. The Owen application does not disclose a defibrillator that sends a defibrillation pulse from an energy storage capacitor network with an overall capacitance and charge voltage that are tailored to patient impedance and the desired energy level. The parties have stipulated that based on this conclusion, judgment should be entered in Plaintiff's favor. (Dkt. No. 92-6.) The Court therefore enters judgment in favor of Plaintiff.

The Court makes the following findings of fact and conclusions of law.

Findings of Fact

A. Procedural Background

1. The technology in Application Serial No. 10/159,806 (the "Owen application") and in U.S. Patent Nos. 5,749,904 (the "Gliner patent") and 6,241,751 (the "'751 patent" or "Morgan patent") relates to methods of external cardiac defibrillation.

2. Interference Number 105,451 at the United States Patent and Trademark Office ("PTO") involved a priority of invention dispute between the '751 patent and the Owen application. Claims 1-37 of the Owen application were copied from the '751 patent to force an interference proceeding.

3. The PTO canceled claims 1-37 of the '751 patent and entered judgment on priority as to the subject matter of the interference to the Owen application.

4. Plaintiff filed this action under 35 U.S.C. § 146, appealing the decision of the PTO in Interference No. 105,451.

5. For purposes of analyzing the adequacy of the written description in the Owen application, the parties agree that a person of ordinary skill in the art would have an undergraduate degree in electrical or biomedical engineering, or an M.D. with some background in electrical or biomedical engineering. (Dkt. No. 92-1 at 18.)

6. At trial, Plaintiff presented the testimony and report of Dr. Patrick Wolf, and Defendant presented the testimony and report of Dr. Mark Kroll.

B. General Background

7. This case involves a dispute over external defibrillators.

8. One problem that must be solved with external defibrillators is accommodating the variation in patient or thoracic impedance encountered when applying a device to a spectrum of patients. The differences in patient impedance lead to two device-related issues.

9. First, more voltage is required to "push" the current through patients having higher impedances. The inventors of the Gliner patent developed a solution to the first problem by using patient impedance as a parameter for selecting a capacitor configuration to deliver a defibrillation pulse to a patient. Their solution uses additional capacitors in a series to provide an appropriate level of voltage for waveform delivery.

10. Second, the range of energy required to defibrillate patients can vary even when patients have identical physical characteristics. Two patients with the same body shape, size, and impedance may take significantly different amounts of energy to defibrillate. The inventors of '751 patent developed a solution to that problem by selecting a capacitor configuration for pulse delivery using both patient impedance and a desired energy level.

C. Patents and Application at Issue

1. The Gliner Patent

11. The Gliner patent discloses a defibrillator that uses multiple capacitor configurations to adjust defibrillation pulses based on patient impedance.

12. According to the embodiments shown in Figures 14-17 of the patent, a sensor measures patient impedance, and based on that measurement, the defibrillator selects a capacitor configuration to use for pulse delivery. By selecting from multiple capacitor configurations, the defibrillator adjusts the current and energy of the delivered defibrillation pulse.

13. Figures 14, 16, and 17 of the Gliner patent disclose three different energy storage capacitor networks with multiple capacitors that can be selectively configured based on patient impedance.

14. By selecting a capacitor configuration based solely on patient impedance, the Gliner patent delivers defibrillation pulses having an energy level that is tailored to the patient impedance. Thus, for a given (or fixed) patient impedance, the energy of a defibrillation pulse will always be the same. For patients with different impedances, the energy output will vary depending on the patient's impedance.

2. The '751 Patent

15. The defibrillator disclosed in the '751 patent is an improvement over the defibrillator disclosed in the Gliner patent. In particular, the '751 patent discloses a defibrillator that uses a second parameter, in addition to patient impedance to select a configuration of capacitors from an energy storage capacitor network. The second parameter is "desired energy level." ('751 patent, Col. 2, lns. 53-60.)

16. Figure 7 of the '751 patent discloses a set of possible capacitor configurations, with capacitors set in parallel and in series. The capacitor configuration can be selected based on patient impedance and the desired energy level. Figure 7 discloses nine possible configurations of capacitors, either in series, in parallel, or some mix of capacitors both in series and in parallel.

17. According to Figure 8 of the '751 patent, the defibrillator measures patient impedance, selects the desired energy level, and uses the patient impedance and the desired energy level to select a capacitor configuration with an appropriate charge voltage and capacitance. ('751 patent Col. 10, ln. 37-Col 11, ln. 5; Id. Col. 2, lns. 57-60.)

18. The selected capacitor configuration is then used to deliver a defibrillation pulse to the patient.

19. To capture the two-parameter aspect of the defibrillation pulse, the inventors of the '751 patent expressly defined the claim term "impedance-compensated defibrillation pulse." The term was defined to mean defibrillation pulses produced from a capacitor configuration whose selection is based on both patient impedance and a desired energy level. After holding a Markman hearing, the Court agreed that the lexicographer rule applied and that the term "impedance-compensation defibrillation pulse" means "a defibrillation pulse produced from an energy storage capacitor network with an overall capacitance and charge voltage that are tailored to patient impedance and the desired energy level." (Dkt. No. 83 at 5.)

3. The Owen Application

20. The Owen application discloses an external defibrillator intended to be used as a wearable external defibrillator.

21. The Owen application has 34 pending claims numbered 1-9, 11-13, 15-18, 20-25, 27-30, 32-33, and 38-39.

22. Claims 1-37 of the Owen application were copied from the '751 patent. Claims 10, 14, 19, 26, and 31 were cancelled and Defendant agrees it will cancel claims 1-4, 13, 15, 20-22, and 38-39 of the Owen application. (Dkt. No. 92-2 at 24-25.)

23. The parties stipulate that the Owen application has an earlier priority date than the '751 patent.

24. Claims 5-9, 11-12, 16-18, 23-25, 27-30, and 32-33 of the Owen application claim a defibrillator that delivers an "impedance-compensated defibrillation pulse," a term which

is given the same definition the Court gave to the term as derived from the '751 patent after claims construction.

25. Claims 5-9, 11-12, 16-18, 23-25, 27-30, and 32-33 expressly recite a defibrillator in which a capacitor configuration is selected based on or in response to patient impedance and a "selected energy level." (Dkt. No. 83 at 7.) The Court construes "selected energy level" as having no meaningful distinction from the phrase "desired energy level."

26. The energy storage capacitor network of the Owen application includes five capacitors.

27. The five capacitors can be switched into three different configurations: a "221" configuration in which two sets of capacitors are in parallel with one in series; a "2111" configuration in which one set of capacitors is in parallel and three are in series; and a "11111" configuration in which all capacitors are in series. Figures 9 to 11 of the Owen application display those configurations.

28. Before delivering a defibrillation pulse, the defibrillator in the Owen application first determines whether there is a shockable rhythm. (See Owen App. ¶ 150.) For example, the invention detects whether the patient is suffering from ventricular tachycardia, ventricular fibrillation, or other treatable rhythms. (See id.)

29. If a treatable rhythm is found, "the processing block **64** may issue commands to charge capacitors **69** to one of a plurality of different levels depending on a determined type of arrhythmia, e.g., ventricular fibrillation versus tachycardia. Thus, if ventricular fibrillation is detected, then a signal having a higher amplitude is output, whereas if a ventricular tachycardia is detected, then a 'cardio' or lower amplitude defibrillation signal is output. Processing block may also issue commands to charge processing block **69**

based on a type of signal to be transmitted, e.g., defibrillation energy, a pacing impulse, or a tactile stimulation signal." (Owen App. ¶ 141.)

30. The Owen application describes "a defibrillation system which includes a defibrillator for delivering predetermined defibrillation energy to a patient. . . ." (Owen App. ¶ 22.) The pulse delivered is thus not tailored to a desired or selected energy level. Rather, the defibrillator sends a predetermined defibrillation energy responsive only to the particular arrhythmia detected and the patient impedance.

31. The Owen application thus discloses a defibrillator with an energy storage capacitor network that selects a capacitor configuration tailored only on patient impedance, not a desired or selected energy. (See Def.'s Proposed Findings ¶ 15 (Dkt. No. 115 at ¶ 15).)

Conclusions of Law

The Owen application does not provide adequate written description for one skilled in the art to know that it describes a device that delivers a defibrillation pulse created by configuring the capacitor network to an overall capacitance tailored to the desired energy level. The Owen application does not disclose using a "desired energy level" as a parameter for selecting a capacitor configuration to tailor the capacitance and charge voltage of a capacitor network. Thus, the Owen application does not adequately describe claims 5-9, 11, 16-18, 23-25, 27-30, and 32-33, which use the term "impedance-compensated defibrillation pulse," a term the Court has defined to require the overall capacitance and charge voltage to be tailored to patient impedance and the desired energy level.

The Owen application does not adequately describe claims 5-9, 11, 16-18, 23-25, 27-30, and 32-33 for the additional reason that those claims specifically recite using a "selected energy level." That is, because the Owen application does not disclose a defibrillator that selects a

capacitor configuration based on a "desired energy level," it fails to describe a defibrillator that selects a capacitor configuration based on a "selected energy level." The written description of the Owen application does not allow a person skilled in the art to understand that the applicants invented what is claimed by claims 5-9 and 11. Similarly, claim 16 and its dependant claims 17-18 are limited to defibrillators that select capacitor configurations for pulse delivery "responsive to a selected energy level." Because the Owen application does not disclose a defibrillator that selects a capacitor configuration responsive to a selected energy level, a person skilled in the art would not understand that the applicants invented what is claimed by claim 16-18. Lastly, claim 23 and its dependant claims 24-25, 27-30, and 32-33 also recite a defibrillator that selects a capacitor configuration "based on said patient impedance and a selected energy level." Because the Owen application does not disclose a defibrillator that selects a capacitor configuration based on a selected energy level, the written description of the Owen application does not allow a person skilled in the art to understand that the applications invented what is claimed by claims 23-25, 27-30, and 32-33.

The Abstract and Summary of the Invention of the Owen application confirm that patient impedance is the only variable for which the device tailors the defibrillation pulse. The Abstract states that "[i]n response to patient impedance and based thereon, the controller can configure a variety of circuit options to deliver a low current flow defibrillation waveform . . . to the patient." There is no mention of tailoring the defibrillation pulse to anything other than patient impedance. Similarly, in the Summary of the Invention the applicant states that "the present invention is a defibrillation system that includes a defibrillator for delivering predetermined defibrillation energy to a patient. . . ." (Owen App. ¶ 22.) If the defibrillation pulse is predetermined, then it cannot also be tailored or customized to a desired energy level.

The Detailed Description of the Preferred Embodiments of the Owen application makes inadequate disclosure to permit one skilled in the art to know the device provides a defibrillation pulse tailored to a desired energy level. For example, paragraph 125 explains that the defibrillation signal is adjusted based on the value of the patient's impedance, not a desired energy level. Paragraph 141 describes setting the defibrillation pulse with a high or low amplitude depending on whether the patient is suffering from ventricular fibrillation or ventricular tachycardia. (Owen App. ¶ 144.) Yet, the summary does not specify with adequate clarity to inform one skilled in the art that the energy storage capacitor network is tailored to the desired energy level. As explained above, a defibrillation pulse that is predetermined cannot be customized or tailored to the operator's desired energy level. At best, this portion of the application speaks to some binary selection between a predetermined high or low charge that is only ultimately tailored to the patient impedance. The Court agrees with Plaintiff's expert, Dr. Wolf, this is inadequate to describe a defibrillation pulse "produced from an energy storage capacitor network with an overall capacitance and charge voltage that are tailored to patient impedance and the desired energy level."

Defendant's reliance on paragraph 200 of the Owen application is equally unpersuasive. (Dkt. No. 114 at ¶ 24.) The only relevant section of that paragraph states the device can perform a test "so as to confirm that defibrillator **10** will automatically terminate an over-current defibrillation . . . and an over-time defibrillation" and that it will perform under-dosage tests, to determine if the defibrillator is providing an under-current defibrillation." (Id. ¶ 200.) This does not speak specifically to tailoring a defibrillation pulse to a desired energy level. Rather, it speaks to ensuring the pulse fits within a high and a low parameter to avoid harming or failing to assist the patient. The Court is not convinced this one skilled in the art would find this

adequately describes a defibrillation pulse "produced from an energy storage capacitor network with an overall capacitance and charge voltage that are tailored to patient impedance and the desired energy level."

Defendant's expert presented unpersuasive testimony that the Owen application sends a defibrillation pulse that is based on patient impedance and a desired energy level. Dr. Kroll testified that the Owen application teaches sending a signal that has a high current when the patient suffers from ventricular fibrillation ("VF"), but a low current when the patient suffers from ventricular tachycardia ("VT"). Dr. Kroll stated that this shows a defibrillation pulse tailored to a desired energy level. Yet, as explained above, this does not show an energy level that is tailored to the energy level desired by or that could be altered by the operator. Rather, it teaches that the pulse will either be high or low depending on the particular arrhythmia that is detected and that a predetermined energy pulse will be delivered, with any tailoring being based only on patient impedance. This is not an adequate written description of the term "impedance-compensated defibrillation pulse," as the Court has defined that term. The Court is not convinced that a person skilled in the art would understand the Owen application to teach a defibrillation pulse that can be tailored to the desired energy level.

Surprisingly, Dr. Kroll made no mention of this theory in his written report. Rather, he argued that generally the device tailored the shock to avoid sending too much or too little current based on "the combination of peak current and pulse duration." (Dkt. No. 92-1 at 20.) Because of this, he argued, "the Owen invention could not be implemented without a consideration of the desired energy. This is due to the requirement to stay away from dangerously high peak currents." (Dkt. No. 92-1 at 30.) In addition, Dr. Kroll expressed this idea in a graph he created, which show that the certain defibrillation pulses can be set by considering patient impedance

alone, but that other pulses would consider the energy level and the patient impedance as to avoid sending an over-current pulse. (Dkt. No. 92-1 at 29.) Yet, this does not show how the Owen application adequately describes to one skilled in the art that the defibrillation pulse can be tailored to a desired energy level. As described above, this only shows that the device operates within a range of energy values to avoid harming the patient, not that it tailors the defibrillation pulse to a desired energy level.

Plaintiff highlights this fact by pointing an exhibit Dr. Kroll created in his deposition, wherein he plotted on his chart four energy pulses described in Table 1 of the Owen application as being part of the preferred embodiment. Based on certain assumptions, Dr. Kroll plotted the points on the chart, showing that none of the pulses in Table 1 required consideration of the desired energy level for them to be produced. This underlines the fact that the device considers energy level only to avoid sending too much current to the patient, not that the device allows the operator to adjust the defibrillation pulse based on the operator's desired energy level.

The twelve paragraphs in the Owen application that Defendant relies on to support its position at trial and its expert's conclusions are unpersuasive. (See Dkt. No. 114 at ¶¶ 25-26.) The Court agrees with Plaintiff and its expert that a person skilled in the art would not understand the defibrillation pulse in the Owen application to be "produced from an energy storage capacitor network with an overall capacitance and charge voltage that are tailored to patient impedance and the desired energy level."

Conclusion

The Court concludes that a person skilled in the art would not find an adequate written description in the Owen application to support claims 5-9, 11, 16-18, 23-25, 27-30, and 32-33. The application fails to provide a written description of a device that sends an "impedance-

compensated defibrillation pulse," as the Court has construed that term. The Court therefore enters judgment in favor of Plaintiff, who is entitled to judgment on priority under 25 U.S.C. § 146.

The clerk is ordered to provide copies of this order to all counsel.

Dated this 25th day of January, 2011.

Marsha J. Pechman
United States District Judge